Message

From: Pierce, Amanda [pierce.amanda@epa.gov]
Sent: 6/8/2020 12:54:56 PM
To: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]
Subject: RE: Jennifer Kuzma and other scholars voice concerns over EPA's May 1st approval of an experimental use permit for GE mosquitoes in Florida and Texas

Hi Mike, I thought you might be interested in seeing Nathan's comment in the article:

Oxitec Response to The Conversation

Oxitec is responding to the article that originally appeared on The Conversation June 3, 2020, entitled "Genetically modified mosquitoes could be released in Florida and Texas beginning this summer – silver bullet or jumping the gun?" and available on https://theconversation.com/genetically-modified-mosquitoes-could-be-released-in-florida-and-texas-beginning-this-summer-silver-bullet-or-jumping-the-gun-139710.

Note: The authors did not attempt to contact Oxitec while writing this article and did not fact check or verify the content of this article. We are responding to a number of factual errors and misleading claims.
The entire team at Oxitec, comprised of individuals from 15 nations, shares these authors' enthusiasm for the potential of genetic engineering to provide solutions to major challenges. Since its inception at Oxford University in 2002, Oxitec has pioneered the safe and responsible use of genetic engineering to control the Aedes aegypti mosquito. This single mosquito species is responsible for the bulk of global transmissions of dengue, Zika, chikungunya, yellow fever and other viral diseases.

Unfortunately, the authors of this article have made a number of false or baseless claims. Most importantly, we disagree with the assertion that the impact of our technology on ecosystems and on human health remains either under-studied or under-regulated. Oxitec's technology has been studied exhaustively by dozens of national regulatory authorities, scientific experts and universities, non-profits, and for-profit organizations around the world. In fact, Oxitec's technology is among the most studied vector control technologies in the world, with more than 100 scientific peer-reviewed publications describing our work.
The authors chose to make a range of inaccurate statements stemming from a recent approval of Oxitec's Experimental Use Permit (EUP) from the U.S. Environmental Protection Agency (EPA) to release our 2nd Generation Aedes aegypti mosquito in two locations in Florida and Texas.

The EPA completed a rigorous, in depth review of thousands of pages of data and supporting scientific literature. The EPA received over 30,000 public comments which were incorporated in their review. In an extra level of transparency, the EPA published its complete risk assessment, its reviews of the planned experimental program, and its complete 150-page response to all of the substantive public comments, on its website and available here: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0355.

At the end of this exhaustive review, the EPA concluded that Oxitec's 2nd Generation Aedes aegypti mosquito carries no risk to human health or to the environment.

The authors claim that the risk assessment process was likely too narrow in its focus but provide no evidence to back up that claim. In reality, the EPA's risk assessment process was wide-ranging, looking at potential impacts on human health and on all relevant environmental and ecosystem impacts (fish, other aquatic life, birds, bats, plants, invertebrates, and other endangered species), and can be read here: https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0274-0359.

The EPA had a range of scientific experts study every aspect of Oxitec's technology for more than 14 months, which came after a year of study on Oxitec's 1st generation technology. The EPA also commissioned the U.S. CDC to be part of Oxitec's application review, furthering the depth of knowledge, expertise and perspective of the team reviewing our technology.

Despite both Oxitec's and the EPA's commitment to transparency, the authors of the article assert that it was difficult to assess how EPA regulators considered public comments, insisting that this was a 'closed' regulatory process. The EPA did not use a closed process. They considered every public comment made and they provided direct, scientific answers to them and made them all available online. There was nothing closed about it.

The authors also decry the absence of local community input in decision-making. However, this ignores the very premise of how vector control works in most countries and certainly in the U.S. The planned Oxitec project in Florida is part of a broader effort by local government mosquito control authorities to ensure they have effective mosquito control tools available in one of the most at-risk counties in the United States. We do not release our mosquitoes just anywhere; we only do so at the behest of and in partnership with local government.

The local mosquito control authorities, together with Oxitec, have carried out years of extensive local consultation and public engagement, including a world's-first non-binding referendum on the issue on the electoral ballot in November 2016. In that referendum, 31 out of 33 precincts voted in favor of releases of Oxitec's 1st Generation Aedes aegypti mosquito (OX513A). Oxitec has subsequently transitioned to an easier-to-deploy 2nd Generation Aedes aegypti mosquito, OX5034, which uses similar genetics, and has received regulatory approval for trials in the U.S. and full biosafety approval in Brazil.

The authors assert in their article that Oxitec's OX513A release plans were withdrawn because of the referendum result in 2016. This is not correct. The referendum results were in fact in favor of releases of Oxitec's mosquitoes, and these are available clearly on the record.

Finally, the authors strangely suggest that a central registry of GM organisms might help with transparency and accountability, similar to clinical trial databases. The reality is that such a database already exists internationally and has for years – the Biosafety Clearing House, organized under the auspices of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. This database has been in existence for more than 15 years. The United States is not a Party to the Cartagena Protocol and therefore does not officially use this international database, but the mechanisms exist, are available for general use, and contain information on Oxitec's mosquitoes (http://bch.cbd.int/database/record.shtml?documentid=115346).

We recognize the importance of both transparency and collaboration between organizations like ours and governments (at the national, state and local levels), and communities when it comes to generating an understanding of and appreciation for the massive benefits that these technologies can deliver to global and local challenges. The U.S. regulatory process, in this case, is functioning in a way that fulfils what these authors are calling for – it is transparent, it has involved the community in decision-making, and it is committed to ensuring that the promise of this technology can reach the people that need it most. Oxitec is proud to have pioneered this new approach to combating a disease vector that has to date rendered most tools incapable of successfully controlling it, but we're even more proud of the women and men from around the world who have come together to develop safe, inspiring world-class solutions with world-class science.

We welcome the authors to contact us to discuss their questions, and we will be reaching out to them to discuss this further. It is not responsible for academics to make loose connections, draw out misleading conclusions, or otherwise attempt to generate quick headlines around topics that require care, thoughtfulness and the hard work of ensuring stakeholders of all types are fully educated on the facts.

We abide by this approach, and we'd hope that those writing articles on these topics would do the same.

Nathan Rose, PhD., Head of Regulatory Affairs, Oxitec Ltd.

From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Friday, June 5, 2020 3:22 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>; Moyer, Adam <moyer.adam@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Striegel, Wiebke <Striegel.Wiebke@epa.gov>; Pierce, Amanda <pierce.amanda@epa.gov>; Wozniak, Chris <wozniak.chris@epa.gov>; Kough, John <Kough.John@epa.gov>; Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>; Reynolds, Alan <Reynolds.Alan@epa.gov>; Kirk, Cassandra <kirk.cassandra@epa.gov>; Welch, Kara <welch.kara@epa.gov>
Subject: Jennifer Kuzma and other scholars voice concerns over EPA's May 1st approval of an experimental use permit for GE mosquitoes in Florida and Texas

FYI -

It's not clear to me they read the risk assessment or response to comments.

Jennifer Kuzma and other scholars voice concerns over EPA's May 1st approval of an experimental use permit for GE mosquitoes in Florida and Texas

- The authors are, "concerned that current government oversight and scientific evaluation of GM mosquitoes do not ensure their responsible deployment."
- The authors propose an official registry for GE organisms released into the environment and suggest a broader set of risks for assessment
- The mosquito release is planned this summer with Oxitec's "2nd Generation Friendly" male *Aedes aegypti*, which mates with females and limits survivability of offspring

The Conversation: Genetically modified mosquitoes could be released in Florida and Texas beginning this summer – silver bullet or jumping the gun?

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